REMARKS

Claims 1, 4, 14-16, 33 and 34 are pending in the present application.

Claims 1, 33, and 34 are amended. Claims 5-13, 17-32 and 35-38, inclusive, have been canceled.

I. Amended Claims 1, 33, and 34.

Claim 1 is amended to specify that the pharmaceutical composition, which is a component of the claimed article of manufacture, contains a pharmaceutically acceptable carrier or excipient and an amount of said nucleic acid sufficient to deliver at least 0.1 grams of human Src protein per 100 grams of pharmaceutical composition. Support for this amendment is found on page 25, line 28, through page 26, line 19, page 26, lines 23-31, and page 27, lines 1-27.

Claims 33 and 34 are each amended to specify that the claimed pharmaceutical composition contains an amount of said nucleic acid sufficient to deliver at least 0.1 grams of the active src protein per 100 grams of pharmaceutical composition. Support for this amendment is found on page 26 of the specification at lines 23-31.

No new matter is added by any of these amendments.

II. Claims 1, 4, and 16 are Patentable over Kato *et al.*

Claims 1, 4, and 16 stand rejected as being anticipated by Kato *et al.* This rejection is unwarranted and should be withdrawn. The Office Action repeatedly characterizes these claims as composition claims, which they are not (see e.g., page 2, last paragraph of the Office Action). Claims 1, 4, and 16 are directed to articles of manufacture, not to compositions.

The articles of manufacture of the present claims must include the following components:

1. packaging material;

2. a pharmaceutical composition contained within the packaging material that is capable of stimulating angiogenesis, and which includes

(a) a nucleic acid encoding for an active human Src protein in an amount sufficient to deliver at least 0.1 of human Src protein per 100 grams of pharmaceutical composition, and

(b) pharmaceutically acceptable excipient or carrier; and

3. a label containing specified printed matter setting forth instructions and directions for use of the composition.

Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick,* 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984). The Kato *et al.* reference does not teach or suggest all of the elements of the claims. This reference does not teach or suggest an article of manufacture containing a packaged pharmaceutical composition that includes a nucleic acid encoding for a human Src protein, and a carrier or excipient, as required by the claims. Nor does this reference disclose the amount of the nucleic acid as being sufficient to deliver at least 0.1 grams of Src protein per 100 grams of composition, as required by the claims. Furthermore, the reference does not teach or suggest the combination of such a pharmaceutical composition and a label that includes the specific printed instructions for use required by the claims.

The Office Action indicates that printed words on a label cannot be given patentable weight unless an intrinsic quality of the article is changed by the written matter. Applicants respectfully submit that this is precisely the case with the present claims. In claim 1, the printed matter on the label should be given patentable weight because the instructions and information on the label impart specific, new functionality to the article of manufacture that was previously unknown to one of ordinary skill in the art. The printed matter would have distinguished the claimed articles of manufacture from any other article containing such a composition, were such article to have been known in the art. Furthermore, the information on the label *vis-a-vis* the ability of active Src proteins to stimulate angiogenesis is novel and informs the user of the article how the article is to be utilized.

The label limitation of the present claims is analogous to the situation in *Miller* where the item at issue was a measuring cup. Without the printed matter, the cup still had a utility of its own. With the printed matter, the measuring cup had a new and distinct utility (facilitating the preparation of fractional portions of a recipe without the need for mathematical

calculations). The printed matter was specifically claimed to be "on" the cup, and this sufficed to provide the structural relationship necessary to carry out the invention. See *In re Miller*, 164 USPQ 46, 49 (CCPA 1969):

> "... printed matter, in an article of manufacture claims, can be given patentable weight ... no attempt is here being made to patent printed matter as such. The fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination ... The solicitor seems to urge that we ignore the claim limitations to the legends because they are printed and because printed matter is not patentable subject matter by itself ... we reject that argument."

Applicants take exception to the Examiner's comments that *Miller* and *In re Gulack* are not applicable here. In *Miller*, prior to adding the printed matter onto the measuring cup, that cup had utility as a simple cup. The new printed matter on the cup conveyed a new utility not previously known to one of ordinary skill in the art. Similarly, *In re Gulack*, 217 USPQ 401, 403 (CCPA 1983) involved a band imprinted with a series of digits derived from a mathematical algorithm. The band could be a hat band, for example, having utility on its own. Before the application of the printed matter, the band could be used as a hat band, or for other purposes. Adding the new printed matter onto the band conveyed a new utility that was not previously known to one of ordinary skill in the art, i.e., it was now useful for performing "magic tricks" and for displaying various aspects of number theory. The CCPA found that the band supported the numbers and the numbers had a relationship to each other that provided a new utility to the band.

Clearly, in the present claims, the printed matter conveys a new utility to an article of manufacture, which utility was not know in the prior art. Furthermore, while the compound (i.e. a nucleic acid encoding Src) may have been known, its inclusion in packaging material in the specified amounts, with a label bearing the specified information, as an article of manufacture, was not known and is not taught or suggested by Kato *et al.* Accordingly, the present claims are patentable over this reference.

III. Claims 1, 14, and 15 are Patentable over Kato *et al.* in View of Boyse *et al.*

Claims 1, 14, and 15 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Kato *et al.* in view of Boyse *et al.* In order to establish a *prima facie* case for obviousness, all claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). That is not the case here. Additionally, "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970). It is black letter law that obviousness is determined at the time the invention was made. In the present case, one of ordinary skill in the art would not have been able to use the claimed articles of manufacture to stimulate angiogenesis, since this concept was unknown to one of ordinary skill in the art at the time the invention was made.

As noted above, Kato *et al.* does not teach or suggest several limitations of the present claims. The combination of Kato *et al.* with Boyse *et al.* suffers from the same deficiencies. Boyse *et al.* merely discloses known techniques for inserting genes into cells; it does not teach or suggest the limitations of the claims that are absent from Kato *et al.* Accordingly, this combination of references would not have rendered the articles of manufacture of the present claims obvious to one of ordinary skill in the art at the time the invention was made.

IV. Claims 33 and 34 are Patentable over Kato *et al.* in View of Boyse *et al.* and GenBank Accession No. X59932.

Claims 33 and 34 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Kato *et al.* in View of Boyse *et al.* and GenBank Accession No. X59932. The combination of these references would not have rendered claims 33 and 34 obvious to one of ordinary skill in the art.

Claims 33 and 34 are directed to pharmaceutical compositions for stimulating angiogenesis comprising a viral (claim 33) or non-viral (claim 34) gene transfer vector containing a nucleic acid and pharmaceutically acceptable carrier or excipient; said nucleic acid having a nucleic acid segment encoding for an active src protein having the amino acid residue

sequence of SEQ ID NO: 5, wherein the pharmaceutical composition contains an amount of said nucleic acid sufficient to deliver at least 0.1 grams of the active src protein per 100 grams of pharmaceutical composition.

While GenBank Accession No. X59932 discloses a protein having the amino acid sequence of SEQ ID NO: 5, the combination of this reference with Kato *et al.* and Boyse *et al.* does not disclose the remaining limitations of the claims. This combination of references certainly would not have suggested to one of ordinary skill in the art at the time the invention was made the specific amount of nucleic acid present in the claimed compositions. Thus, the presently claimed composition would not have been obvious based on this combination of references.

V. Conclusion

Claims 1, 4, 14, 15, 16, 33, and 34 are patentable over the applied art. Reconsideration of the finality of the rejections and early passing of this application to issue is earnestly solicited. In the event that the foregoing is deemed unpersuasive, Applicants request that the present amendment be entered to place the application in better form for appeal.

Respectfully submitted,

Dated: June 23, 2004

By _____
Talivaldis Cepuritis (Reg. No. 20,818)

OLSON & HIERL, LTD.
20 North Wacker Drive
36th Floor
Chicago, Illinois 60606
(312) 580-1180

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this AMENDMENT AND RESPONSE UNDER RULE 116 is being transmitted by facsimile transmission to Fax No. 703-872-9306 on June 23, 2004.

_____
Talivaldis Cepuritis (Reg. No. 20,818)